DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-240-4500
FAX: 504-240-4566

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M30160

September 30, 1999

WARNING LETTER NO. 99-NOL-49

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Ms. Lena D. Saltzman, President
Lena's Cajun Seafood Dishes, Inc.
34631 Ellis Bridge Road
Gueydan, Louisiana 70542-5707

Dear Ms. Saltzman:

On February 23 and March 4, 1999, a U.S. Food and Drug Administration (FDA) investigator conducted an inspection of your frozen seafood dinner manufacturing plant, located at 34631 Ellis Bridge Road, Gueydan, Louisiana. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, *Code of Federal Regulations* (CFR), Part 123 and the Current Good Manufacturing Practice (CGMP) regulations for foods, Part 110. This causes your finished product, frozen seafood dishes, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the February 23 and March 4, 1999, inspection, the FDA investigator observed shortcomings in your system that were nearly identical to those pointed out in the June 1 - 2, 1998, inspection, and stated in the untitled letter sent to your firm on July 8, 1998. The FDA investigator also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA-3501) and the Form FDA-483, which presents his evaluation of your firm's performance

regarding various aspects of the HACCP and CGMP requirements. The Form FDA-483 is enclosed for your review. The observations of concern to us are as follows:

- Your firm has not met the requirement of Title 21, CFR, Part 123.9(c) to make your HACCP plan available for official review. We request that you send us a copy of your current HACCP plan at the address provided below. As you know, a HACCP plan is required for the control of pathogens in your seafood products, i.e. seafood gumbo, crawfish etouffee, crawfish bisque, crab/shrimp pie, and shrimp stuffed bell pepper, which are cooked, ready to heat and serve, and sulfites in your shrimp products which contain sulfites;

- Failure to have monitoring records documenting that the food safety hazards are controlled at each Critical Control Point, as required by Title 21, CFR, Part 123.6(b) and Title 21, CFR, Part 123.6(c)(7). The cooking process is designed to eliminate pathogens, which can be introduced to your product during the preparation of your seafood mixtures. It is imperative that you maintain records of the cooking time and maximum temperature achieved in this process to document that you are controlling this potential hazard. The cooling step is a critical step in your process and requires strict control and monitoring to ensure that the seafood products are cooled quickly and sufficiently so as to limit pathogen growth; and,

- Failure to adequately monitor exclusion of pests, protection from adulterants, and proper labeling, storage and use of toxic compounds, as required by Title 21, CFR, Part 123.11(b).

As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the Form FDA 483. However, you should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have any questions regarding the implementation of the HACCP regulations, you may contact Mrs. Hardin at (504) 240-4500.

Sincerely,

James E. Gamet
District Director
New Orleans District

Enclosure: Form FDA 483